MAR-25-2003 09:21

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 0 3 — 0 7

2. STATE: Maryland

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) Medicaid

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE P&I
December 1, 2002
~~October 1, 2002~~

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
See Attached

7. FEDERAL BUDGET IMPACT:
a. FFY 2003 $ [redacted] (1.75 Million)
b. FFY 2004 $ [redacted] (2 Million)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1A
Pages 25, 25-1, 26, 26-1, 27, 27A, 27A-1
Attachment 4.19 A&B
Pages5a, 6a, 7A, & 8

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Same (See Attached)

10. SUBJECT OF AMENDMENT:
These amendments add ergocalciferol liquid to the list of covered non-legend drugs, ease the restrictions on how long a prescription can be filled after it is written, change the copay, and increase number of refills allowed among other things (see attached)

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Susan J. Tucker, Executive Director
Office of Health Services

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Arlene H. Stephenson

13. TYPED NAME:
Arlene H. Stephenson

14. TITLE:
Acting Secretary

15. DATE SUBMITTED:
December 26, 2002

16. RETURN TO:
Susan J. Tucker, Executive Director
OHS - DHMH
201 West Preston Street, Suite 124
Baltimore, Maryland 21201

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: December 27, 2002

18. DATE APPROVED: March 25, 2003

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
December 3, 2002

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:
Mary T. McSorley

22. TITLE:
Associate Regional Administrator
Division of Medicaid and Children's Health

23. REMARKS: REQUEST P&I CHANGE
AS PER R.O. P&I CHANGE TO PROPOSED EFFECTIVE DATE FROM 10/1/02
TO 12/3/02

FORM HCFA-179 (07-92)

Instructions on Back

STATE PLAN OF MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE OF MARYLAND

PROGRAM	LIMITATIONS
12. A. Prescribed Drugs	A. The following are not covered: 1. Non-legend drugs other than; insulin, Schedule V cough preparations, ergocalciferol liquid, family planning products and enteric coated aspirin used in the treatment of arthritic conditions, sole ingredient oral ferrous sulfate products and, for individuals 12 years of age or younger, chewable tablets of iron in combination with vitamins and/or other minerals and any other cost effective medications as specified in Program regulations. 2. Medical supplies and durable equipment, except needles and syringes, family planning supplies and those supplies used in the preparation of compounded prescriptions for home intravenous therapy; 3. Any original prescription for a controlled substance dispensed more than 30 days after the prescribing date and 120 days after the prescribing date for a non-controlled substance; 4. Drugs supplied to hospital inpatients – (drugs for hospital inpatients are covered under the Hospital Inpatient Program); 5. Drugs and supplies, dispensed by the provider, which are acquired by the provider at no cost; 6. Experimental or investigational drugs; 7. Injectables dispensed by a provider for administration by the prescriber (drugs administered by the prescriber are covered under the Physicians Program) except when authorized by the Department to be covered under the Pharmacy Program; 8. Food supplements or infant formula; 9. Sugar and salt substitutes;

STATE PLAN FOR MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE OF MARYLAND

PROGRAM	LIMITATIONS
(continued) 12. A. Prescribed Drugs	10. Cosmetics, medicine chest supplies and sundries including all soaps, all body powders, all body oils or body lotions, cotton balls, adhesive strip bandages, cotton-tipped applicators, suntan products, deodorants, dentrifices, tissues, convenience packages of covered items, hot water bottles, ice caps, heating pads, soft cervical collars; 11. Alcoholic beverages; 12. Ostomy supplies; 13. Those services authorized for payment to a prescriber, hospital, nursing facility, hospital outpatient department or free-standing clinic; 14. Medical Assistance prescriptions and injections for central nervous system stimulants and anorectic agents when used for weight control; 15. Drug products for which Federal Financial Participation is prohibited pursuant to 42CFR441.25; 16. Drug products marketed by a manufacturer or distributor who has not entered into a rebate agreement with the Secretary of the Department of Health and Human Services as described in Section 1903 of the Social Security Act or a manufacturer who has not signed a rebate agreement with the State of Maryland prior to April 1, 1991, except Coverage will be allowed for single source drugs and innovator multiple source drugs if: i. The State has made a determination that the drug is essential to the health of the beneficiaries;

STATE PLAN FOR MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A Prescribed Drugs Preauthorization Requirements	B. The following are not covered except where preauthorization has been obtained from the Department or its designee: 1. Medical Assistance prescriptions or injections for male hormones for biologic females; 2. Medical Assistance prescriptions or injections for female hormones for biologic males; 3. Medical Assistance prescriptions for enteral nutritional products including vitamins and minerals when administered in the home by means of nasogastric, jejunostomy or gastrostomy tube. 4. Drugs rejected by the point-of-sale system because of edits established by the Program to ensure appropriate utilization of medication before the prescription is dispensed, where the Department does not allow provider level over-rides, including but not limited to drug-drug interactions, early refill, therapeutic duplication, and maximum quantity; 5. Growth hormone; 6. Palivizumab; 7. Drugs identified by the Program that are subject to fraud or abuse. 8. Non-maintenance drugs for more than a 34 day supply. 9. Antibiotic liquids requiring reconstitution for amounts exceeding a 14 day supply. 10. Products with a usual and customary charge exceeding $400 except for home intravenous therapy.

STATE PLAN FOR MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A. Prescribed Drugs Preauthorization Requirements	NOTE: A response to prior authorization requests is provided within 24 hours of the requests. Providers are required to provide at least a 72 hour supply of covered outpatient prescription drug in an emergency situation. The provider or the prescriber, if appropriate, ordering a drug subject to preauthorization shall contact the Department or its designee, through an established 24-hour hot-line, to request preauthorization and shall provide required information and documentation. C. Limitations to Covered Services: 1. The allowable cost of ingredients dispensed pursuant to a prescription may not exceed an upper limit as established in Attachment 4.19 A & B. 2. Refills: a. The prescriber shall authorize refills on the original prescription.

TN# 03-7
Supersedes TN# 93-4

Approval Date MAR 25, 2003
Effective Date DEC 3, 2002

STATE PLAN OF MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A Prescribed Drugs	b. The Program will authorize no more than 11 refills for non-controlled drugs, no more than 5 refills for Schedule III-V controlled drugs and no refills for Schedule II drugs; c. Only the original provider may dispense refills; d. A compounded prescription for home intravenous therapy is subject to the following limitations: (i) A prescriber's order is valid for the duration of therapy prescribed, but the duration of a single order may not exceed 100 days; and (ii) All claims submitted require new prescription numbers; e. Prescriptions are limited to a 34 days supply at one time except for: (i) Birth control pills which are limited to a 6-cycle supply at one time; (ii) Oral sodium fluoride used in the prevention of dental carries are limited to an original prescription of up to 120 days supply with up to two refills, not to exceed a total of 360 days supply; and (iii) Maintenance drugs as specified in Pharmacy Services Regulations may be dispensed in up to a 100-day supply at one time. 3. The total treatment time covered by the original prescription and its refills, may not exceed 360 days for non-controlled drugs, 180 days for Schedule III-V controlled drugs, and 100 days supply for Schedule II controlled drugs . 4. When the drug product is prescribed by its non-proprietary or generic name, the provider shall dispense the least expensive product of equal therapeutic effectiveness available;

STATE PLAN OF MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A. Prescribed drugs	5. Co-Payment (a) There will be a $2 co-payment by recipients for each covered service, except for the following: (i) Individuals under 21 years old; (ii) Pregnant women; (iii) Institutionalized individuals who are inpatients in long term care facilities or other institutions requiring spending all but a minimum amount of income for medical costs; (iv) HMO enrollees; (v) Family planning drugs and devices; (vi) Prescriptions for waiver-eligible recipients as defined in Managed Care Eligibility and Enrollment Regulations 10.09.63.01A (vii) Drugs for recipients enrolled in Rare and Expensive Case Management under COMAR 10.09.69; (viii) Generic drugs. (b) Services cannot be denied to any eligible recipient because of the individual's inability to pay the co-payment. This requirement does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the copayment charges. A recipient is deemed unable to pay the co-payment if the recipient states to the pharmacist that he or she cannot pay. Pharmacists may not make any inquiry or investigation into the recipient's ability to pay.

TN# 03-7
Supersedes TN# 99-3

Approval Date MAR 25, 2003
Effective Date DEC 3, 2002

STATE PLAN OF MEDICAL ASSISTANCE
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A Prescribed Drugs	6. Nursing home prescriptions (a) Claims shall be identified as nursing home prescriptions by coding mechanisms determined by the Program; (b) Credits, less the paid dispensing fee, for unused unit dose medication and any other medication which may legally be returned to stock shall be made within 60 days of Program payment and include adjustments for leave of absence prescriptions; and (c) Multiple prescriptions dispensed to a recipient residing in a nursing home for the same drug product or compounded prescription shall receive only one professional fee per calendar month except for: (i) Leave of absence prescription, (ii)Compounded prescriptions for home intravenous therapy, and (iii)Prescriptions for Schedule II-IV controlled dangerous substances. 7. Preauthorization is not required for: (a) Prescriptions for oral contraceptive drug products; (b) Drugs dispensed in unit dose form to patients in a nursing facility by a provider using an approved unit dose system.
12. B. Dentures See "Limitations" Item 10, "Dental Services"	

TN# 03-7
Supersedes TN# 99-3

Approval Date MAR 25, 2003
Effective Date DEC 3, 2002

g. (reserved)
h. Determination of allowable cost;

(1) For multiple source drugs listed on the Program's Interchangeable Drug List, allowable cost shall be the lowest of:

(a) The Interchangeable Drug Cost (IDC) which is the maximum amount the Program will reimburse for selected, approved interchangeable multiple source drugs determined by any of the following:

(i) Lowest estimated acquisition cost of the generically equivalent products available in the State;

(ii) Price obtained by:

(aa) Ascertaining the lowest cost from among the approved interchangeable multiple source products from each wholesaler that the Program has current and accurate pricing information, and

(bb) Selecting as the IDC the highest of the costs ascertained in (aa) above; or

(iii) Price from a commercial generic pricing source.

NOTE: Maximum allowable costs will be reviewed and updated:

(aa) At least once every year,

(bb) Whenever there is an emergency recall by the Food and Drug Administration, or

(cc) Temporarily, if there is an acute shortage of supply from available sources.

judgment, a specific brand is medically necessary, the EAC of the specified brand shall be the allowable cost.

(4) For condoms dispensed by Pharmacy providers, the allowable cost shall be the EAC established by the Department based upon the AWP of the lowest price products generally available.

(5) For covered over-the-counter drugs, except those specified in section i. below, allowable cost shall be based on the AWP of the item.

(6) For medical supplies and equipment, the allowable cost shall be based on the AWP of the item.

i. Payment for covered services to a pharmacy will be made as follows:

(1) Payment for legend drugs, Schedule V cough preparations, enteric coated aspirin, ergocalciferol liquid, and oral ferrous sulfate products will be the lower of:

(a) The providers charge according to section f above; or

(b) The allowable cost of the item in section h, above, plus a professional fee.

(2) Payment for over-the-counter drugs except for enteric coated aspirin, ergocalciferol liquid, oral ferrous sulfate products, and chewable tablets of ferrous salts in combination as described shall be the lowest of:

(b) The upper limit established by the Department based upon the lowest price at which the product is generally available throughout the State.

(7) Recipient co-payment of $2 per order will be deducted from the payment where applicable in (1), (2) and (3) and (6) above.

(8) The Department may pay providers using an approved unit dose system on the basis of a daily or monthly dispensing fee per nursing home resident. The value of these fees may not be higher than the pharmacists' usual and customary charge to the non-Medicaid patients for similar services. Payments to nursing facilities will not exceed, in the aggregate, the FGUL.

j. The professional fee is a variable fee based on the type of prescription and is $3.69 for brand name drugs and $4.69 for generic drugs except for prescriptions for compounded home intravenous therapy and prescriptions for recipients residing in nursing homes. For compounded prescriptions for home intravenous therapy the professional fee is $7.25. For prescriptions for recipients residing in nursing homes that are not compounded for home intravenous therapy, the professional fee is $4.65 for brand name drugs and $5.65 for generic drugs.

k. Payment for covered services to a physician or osteopath shall be make as follows:

(1) Payment for legend drugs, Schedule V cough preparations, over-the-counter drugs including enteric coated aspirin, ergocalciferol liquid and oral ferrous sulfate products shall be the lower of:

(a) The physician's or osteopath's charge according to g, above; or

(b) The allowable cost of the item in h. above.

(2) Recipient co-payment of $2 per order will be deducted from the payment where applicable.

l. Reimbursement to a licensed physician for dispensing covered drugs to Medicaid recipients will be on the same basis as reimbursement to a registered pharmacist, if:

(1) The physician dispenses drugs on a regular basis in the physician's office;

(2) The physician's office is not located within a 10 mile radius of a Medicaid participating pharmacy; and

(3) The Medical Assistance Program, after a consultation with the Board of Pharmacy, has verified that the physician is dispensing medication in accordance with accepted pharmacy standards.

m. Payment will be made only for drugs supplied by manufacturers that have a signed national agreement or an existing approved agreement with the State, as set forth in Attachment 3.1A.

n. The State will not pay for:

(1) Prescribed drugs as described in Attachment 3.1A, Prescribed Drugs, Limitations.

(2) Products that are not medically necessary or life sustaining or are essentially cosmetic in nature.